

My5-FU









My5-FU™ Sample Stabilizer

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Key to Symbols Used

IVD	<i>in vitro</i> Diagnostic Device		Consult Instructions for Use
REF	Catalog Number		Use By
LOT	Batch Code		Temperature Limitation
	Manufacturer		Flammable
	Caution: Consult accompanying documents		Serious Health Hazards
			Health Hazards
CH REP	Authorized Representative in Switzerland		
EC REP	Authorized Representative in the European Community		


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Intended Use

The Saladax My5-FU Sample Stabilizer is intended to stabilize 5-fluorouracil in blood samples collected for analysis in the My5-FU Assay. The Sample Stabilizer is intended to ensure sample integrity from draw through analysis.

Contents

The My5-FU Sample Stabilizer vial contains 10 mL of a dihydropyrimidine dehydrogenase inhibitor in a 30% methanol solution.

Additional Required Equipment (not provided)

- EDTA or heparin tube for collection of ≥ 2 mL of blood
- 25G 1" BD Eclipse™ safety needle or other safety needle ≥ 1 " long, 25G or narrower
- 1 mL BD Luer-Lok™ disposable syringe or other 1 mL Luer-lock disposable syringe

Storage and Shelf life

Store the My5-FU Sample Stabilizer vial at ambient temperature. The My5-FU Sample Stabilizer is stable until the expiration date when stored as directed.

Warnings and Precautions

For In Vitro Diagnostic Use.

Handle and dispose of sharps (needle) in accordance with applicable regulations.

Limitations of the Procedure

Sample integrity and accurate results with the My5-FU Assay are dependent upon the proper storage and use of the My5-FU Sample Stabilizer as directed.

The sample stabilizer must be injected into the blood collection tube immediately after collection. Prepare the stabilizer for injection *before* drawing the blood sample.

After collecting the blood and injecting the collection tube with the stabilizer, **DO NOT** place the sample on ice and **DO NOT** refrigerate the sample. This may result in an increase in interference from hemolysis leading to erroneous 5-FU results.

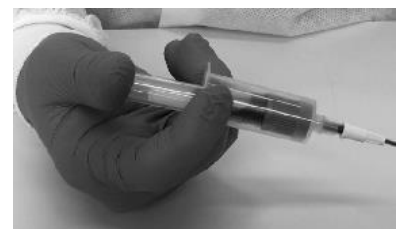
Instructions for Use

- Refer to the Saladax My5-FU Assay package insert for a complete summary and explanation of the test.
- Attach a safety needle to a 1 mL Luer-lock syringe. Set the plunger to 0.1 mL.
- Uncap the needle; place the cap aside for later use.
- Insert the needle into the My5-FU Stabilizer vial through the septum. Depress the plunger completely.
- Draw 0.1 mL of the stabilizer into the syringe.
- Recap the needle. The Sample Stabilizer is now ready for use.
- COLLECT ≥ 2 ML OF BLOOD into an EDTA or heparin tube by venipuncture or through a peripheral IV.

DO NOT use plasma separator tubes.

DO NOT draw from the drug infusion port.

DO NOT do a short draw.



- INJECT COLLECTION TUBE WITH THE SAMPLE STABILIZER immediately after draw and gently invert 3 times. CENTRIFUGE SAMPLE WITHIN 24 HOURS of the draw.

DO NOT place sample on ice and **DO NOT** refrigerate when using the stabilizer.

DO NOT test any sample that was not treated with the stabilizer.

DO NOT test any sample that was not centrifuged within 24 hours.

- CAREFULLY DRAW OFF PLASMA from the top of the tube, avoiding cell layer and transfer to a capped secondary tube. Plasma must be free of cells. Store the plasma sample at 2-8°C or room temperature for up to 1 week or freeze ($\leq -20^{\circ}\text{C}$) if storing the sample longer.
- SAMPLE CAN BE SHIPPED AT AMBIENT TEMPERATURE. Provide the laboratory with the times of infusion start and finish.

